

# A greed approach on implementation of the PRIMO model rev. 3.1. - PAFF residues 25-26 November 2019, agenda item 5.

## A.05 Implementation of revisions of PRIMo model

- **Routine MRL applications under Art. 6-10 of Regulation (EC) No 396/2005, MRL assessments within the EFSA peer review process and Art. 12 MRL reviews:** EFSA starts using the newest version (revision 3.1), as from **1 January 2020 onwards** (date of adoption of the EFSA RO (Art. 10, Art. 12) or EFSA Conclusion (peer review)) for all ongoing assessments regardless of the time of submission of the application or the time of data call-in under Art. 12. Generally, EFSA will also do the **PRIMO re-calculations** for those assessments where the ER are already finalised by the MS and which are at preparation stage in EFSA, except in those cases:
  - For assessments for which an experts's discussion has not yet been undertaken: EFSA will ask RMS to update the PRIMo calculation accordingly within the process, either during the column 4 step or during the RMS homeworks.
  - For assessments within the peer review for which an experts' discussion has already been undertaken (i.e. under drafting stage or exceptional ED clock stop): RMSs will be asked to update the PRIMo calculations with new revision 3.1
  - Where this would lead to **exposure issues** that would **prevent the Commission from setting a new/modified MRL or to maintain an MRL in the Article 12 assessment**, so specifically in **cases where originally we had decided to still apply rev. 2**, time will be allowed to the applicant to **submit a fall-back GAP** (e.g. **Art. 10 applications submitted before February 2018**, incl. some that are on **clock stop**).
  - **Specific case: Confirmatory data assessments under Article 12:**
    - For a specific substance for some crops confirmatory info may have been requested, for other crops this may not be the case.
      - Crops subject to the assessment: If with Primo rev. 3.1. a concern is identified: stop –clock possible (EMS/applicant can supply info on a fall back GAP, normally a short 2 months period is given, but which could be a little more flexible to allow the applicant to prepare already existing information for submission for which the 2 months may be too short). The flexibility should not be given to allow the applicant to generate completely new data.
      - Crops not subject to the assessment: acute exposure should not be re-assessed with Primo rev. 3.1 . If a chronic risk is identified with Primo

rev. 3.1 in which both types of crops are of course taken into account, EFSA will report the problem for consideration of risk managers.

- **Assessments will not be re-opened** in cases where the EFSA RO's are already published but no risk management decision has been taken, neither where the process was already closed in the past by a Regulation.
- For the **CCPR Report – first batch** – work is close to finalisation:
  - For the active substances assessed in the extraordinary meeting, EFSA updated the most recent RA performed for the substance by EFSA. Hence, if the Art. 12 or the most recent Art 10 assessment was performed with PRIMo 2, EFSA calculated the scenario for the Codex MRLs also with PRIMo 2. This work is too advanced and close to deadline and will not be changed.
  - In other cases Primo 3.1 was already used, e.g. if there was no previous RA
- For the **CCPR report – second batch** to be discussed in the second and third Council Working Party: EFSA will use Primo rev. 3.1. in all cases.